

REMARKS**Status of Claims**

Claims 1, 4-9, 12-13, 18-19, and 76-90 are pending after entry of this paper. Claims 2-3, 10-11, 14-17, and 20-75 have been cancelled without prejudice. Applicant reserves the right to pursue cancelled claims in at least one continuing application.

No claim has been amended.

Rejection Under 35 USC § 103(a)

Claims 1, 4-9, 76-84, 89 and 90 have been rejected under 35 USC 103(a) for allegedly being unpatentable over Lingnau et al (WO 01/54720) ("Lingnau"). Applicant respectfully disagrees with the present rejection for at least the reasons set forth below.

As an initial matter, applicant asserts that the Examiner has not demonstrated how each and every element of the present claims would have been obvious in view of the cited reference. Specifically, the Examiner has not provided any arguments regarding the claim element "wherein the microparticulate complex is a precipitate". Applicant asserts that this claim element is not taught or suggested in Lingnau. Furthermore, applicant asserts that it would not have been obvious to a person of ordinary skill in the art to prepare a microparticulate complex as a precipitate at the time the application was filed. Therefore, applicant asserts that the rejection is improper because the Examiner has failed to demonstrate how each and every claim element would have been obvious to a person of ordinary skill in the art at the time the present application was filed.

Additionally, applicant asserts that Lingnau is directed to a composition that comprises (1) an antigen, (2) an immunogenic oligonucleotide, and (3) a polycationic polymer. Applicant respectfully directs the Examiner's attention to the following citations in Lingnau:

Pharmaceutical composition for immunomodulation and preparation of vaccines comprising an antigen and an immunogenic

oligodeoxynucleotide and a polycationic polymer as adjuvants. (Lingnau, Title)

This objective is solved by a pharmaceutical composition comprising

- an antigen or an immunosuppressing agent
 - an immunogenic ODN, containing CpG motifs, and
 - a polycationic polymer
- (Lingnau, page 7)

The combination of antigen, immunogenic ODN and polycationic polymer allowed the generation of superior vaccines as compared to vaccines consisting of immunogenic ODN and antigen or antigen and polycationic polymer. (Lingnau, page 7).

etc.

Thus, Lingnau clearly teaches that all three elements must be present in the composition. Accordingly, applicant asserts that the present claims are not obvious in view of Lingnau because the present claims do not require the addition of a separate polycationic polymer.

Applicant also notes that the "polycationic polymer" of Lingnau is not the same as the "peptide immunogen" required by the present claims. In the Office Action, the Examiner states that "Lingnau et al teaches the use of poly-L-arginine (cationic peptide) and CpG-ODN 1668 (anionic CpG) synergistically enhances an immune response to an antigen contained in said composition ... [t]he poly-L-arginine ... utilized in the cited prior art is considered to fall under the definition of cationic peptide ... in instant claim 1" (Office Action, page 3). Applicant respectfully disagrees with the Examiner's contentions and believes that the Examiner has mischaracterized the teachings of Lingnau. Specifically, the Examiner incorrectly equated the polymer disclosed in Lingnau with the immunogen of the present claims. Applicant asserts that the cationic peptide immunogen of the present claims is patentably distinct from the cationic polymer of Lingnau, which is not immunogenic. Applicant notes that the immunogen/polymer difference is a significant distinction between the present claims and Lingnau.

Furthermore, applicant notes that Lingnau does not teach or suggest that a peptide immunogen must be cationic. In fact, all of the peptide immunogens disclosed in Examples 1-5 of Lingnau (except for MC1R in Example 3) are either anionic or neutral. Therefore, applicant

asserts that Lingnau does not provide any teaching or guidance that the peptide immunogen must be cationic.

Moreover, with regard to the single cationic peptide studied in Lingnau, MC1R, Lingnau states “[w]hile the injection of MC1R-peptide with ... CpG-ODN alone leads to low numbers of peptide-specific IFN- γ -producing cells, the injection of MC1R-peptide with the combination of poly-L-arginine and CpG-ODN strongly enhances the peptide-specific response.” (page 20) (emphasis added). Thus, based on this finding, applicant asserts that a person of ordinary skill in the art would not have been motivated to modify Lingnau to remove the polycationic polymer from the composition. Furthermore, applicant respectfully directs the Examiner’s attention to the MPEP which explicitly states:

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. (M.P.E.P. § 2143.01(V) (citing In re Gordon, 733 F.2d 900 (Fed. Cir. 1984)).

Interestingly, in In re Gordon the Federal Circuit stated:

We are persuaded that the board erred in its conclusion of prima facie obviousness. ... The question is ... whether it would have been obvious from a fair reading of the prior art reference as a whole to [make the proposed modification]. ... The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification. In re Gordon, 733 F.2d at 902.

In view of the MPEP guidelines, applicant asserts that a person of ordinary skill in the art would not have been motivated to modify the composition disclosed in Lingnau to remove the polycationic polymer, because doing so would render the Lingnau composition being modified unsatisfactorily for its intended purpose. Therefore, applicant asserts that Lingnau teaches away from using a composition without a polycationic polymer.

Finally, the Examiner argues that “the specific pH, ratios, concentrations, and particle size ... would have been obvious” (Office Action, page 3). However, the Examiner has not provided any evidence to support this conclusory statement. Furthermore, Lingnau does not

provide any disclosure regarding the pH, peptide immunogen:CpG oligonucleotide charge ratios, or the average particle size. Applicant respectfully directs the Examiner's attention to MPEP 2142, which states:

The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

Applicant asserts that the Examiner only provided conclusory statements and did not provided any articulated reasoning on how four elements of the present claims (i.e., pH, ratios, concentrations, and particle size) would have been obvious. Therefore, the Examiner has failed to establish how each and every claim element would have been obvious to a person of ordinary skill in the art at the time the application was filed.

In view of the above-mentioned remarks, applicant asserts that Lingnau, applied alone or combined with the knowledge of a person having ordinary skill in the art, does not teach or suggest each and every element of the present claims. Additionally, the Examiner has not demonstrated how each and every claim element would have been obvious as of the filing date of the present application. Moreover, applicant asserts that the explicit teachings of Lingnau teach away from the composition of the present claims. Therefore, applicant respectfully requests reconsideration and withdrawal of the 35 USC 103 rejection to the claims.

Response to Claim Objections

Claims 12, 13, 18, 19, and 85-88 have been objected to for depending from rejected claims. For at least the reasons set forth above, applicant asserts that Claims 1, 4-9, 76-84, 89 and 90 are non-obvious and patentable over the reference cited by the Examiner. Accordingly, applicant respectfully requests reconsideration and withdrawal of the claim objections.

Dependent Claims

Applicant has not independently addressed all of the rejections of the dependent claims. The applicant submits that for at least similar reasons as to why independent claims, from which all of the dependent claims depend, are allowable as discussed above, the dependent claims are also allowable. Applicant, however, reserves the right to address any individual rejections of the dependent claims and present independent bases for allowance for the dependent claims should such be necessary or appropriate.

CONCLUSION

Based on the foregoing amendments and remarks, applicant respectfully requests reconsideration and withdrawal of the rejection of claims and allowance of this application.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **504827**, Order No. 1004263.156US.

Respectfully submitted,
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